II. Claims 17 and 65-69, drawn to a method for preparing a monoclonal antibody comprising immunizing a mammal with a NIK peptide and growing a clone hybridoma comprising a spleen cell from said mammal.

III. Claims 39-47 and 70-81, drawn to a method of regulating NIK activity and a method of treating a disease caused or aggravated by NIK activity comprising administering an anti-NIK antibody.

IV. Claims 48-56, drawn to a composition of matter comprising a substrate covalently attached to a NIK peptide.

V. Claims 82 and 83, drawn to a method for purifying a NIK binding protein.

The Examiner also has required an election of species requirement with respect to "a specific portion of the amino acid to which the antibody binds." If Group III is elected, Applicants are further required to elect one disease recited in claim 80.

The Requirement for Restriction Should be Withdrawn.

Unity of invention in a U.S. national-stage application under 35 U.S.C. § 371 is governed by 37 C.F.R. § 1.475, and a lack of unity may result in a restriction requirement. 37 C.F.R. § 1.499. Rule 475 provides that, even where a group of inventions is claimed in an application, the unity of invention requirement is satisfied if there is a unifying technical relationship involving "one or more of the same or corresponding special technical features." "Special technical features" are "technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art." *Id.* The Patent Office guidelines relating to double patenting rejections apply to national-phase applications submitted under 35 U.S.C. § 371. M.P.E.P. §§ 823 and 1893.03(d).

The Office asserts that the technical feature uniting Groups I-V is an anti-NIK antibody, which was assertedly disclosed in U.S. Patent No. 5,854,003 ("the '003 patent") prior to the instant application. On the contrary, the NIK peptide disclosed in the '003 patent is a mutant peptide comprising a different amino acid sequence from that of the instant

application. In particular, the peptide of the '003 patent contains a substitution at position 25 compared to the NIK sequence of the instant application. Compare, e.g., SEQ ID NO: 2 of the '003 patent with SEQ ID NO: 21 of the instant application. To the extent that the '003 patent discloses fragments of the mutant NIK comprising the substitution at position 25 (see, e.g., column 3, lines 9-14), the disclosure does not destroy the special technical feature of the instant claims. Thus, the general description of antibodies that bind NIK in the '003 patent refers to antibodies directed against a different peptide than the anti-NIK antibody of the instant application, and does not anticipate or render obvious the anti-NIK antibody unifying the pending claims. Accordingly, the claims of Groups I-V share a special technical feature, and should be examined together.

The Office also required an election of species with respect to the particular NIK region bound by the claimed antibody. At the very least, SEQ ID NO: 11 and SEQ ID NO: 12 should be examined with SEQ ID NO: 7. As noted in the instant application, SEQ ID NOs: 7, 11, and 12 are located in the flanking region of the kinase domain of human NIK (see, e.g., page 17, lines 14-16 and 25-31). Antibodies that bind the flanking region can efficiently detect NIK by Western blotting analysis (page 17, lines 25-31). The '003 patent does not teach or suggest an antibody that binds the flanking region of the NIK kinase domain. As such, an anti-NIK antibody that binds SEQ ID NOS: 7, 11, or 12 defines a contribution over the art. Thus, at the very least, claims directed to SEQ ID NOS: 11 and 12 (i.e., claims 5, 6, 13, 22, 23, 25, 26, 28, 29, 33, and 34) should be examined together with claims 1-4, 7-11, 14-16, 19-21, 24, 27, 30-32, and 35-38.

In view of the above, the restriction requirement imposed for asserted lack of unity of invention should be withdrawn in its entirety. Alternatively, claims 1-11, 13-16, and 19-38 (corresponding to Group I) should be examined together without requiring a species election.

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Respectfully submitted,

By _____

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